ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in §413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in §494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under §410.50 and §410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered ''renal dialysis services,'' and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

[75 FR 49198, Aug. 12, 2010]

§413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in §413.171 and home dialysis services as defined in §413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in §413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in §413.174(b) and §413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in §413.196(b) in the FEDERAL REGISTER.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates*. CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. CMS determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in § 414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in § 414.313.

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

(1) Only on an assignment basis, directly to the facility which must accept, as payment in full, the amount that CMS determines;

(2) Subject to the Part B deductible and coinsurance;

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in § 414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in § 405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biological furnished by independent ESRD facilities is based on the methodology specified in § 414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in § 413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2016, payment to an ESRD facility for renal dialysis service drugs and biologicals with only

an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 69935, Nov. 19, 2008; 75 FR 49198, Aug. 12, 2010; 78 FR 72252, Dec. 2, 2013]

§413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

[75 FR 49199, Aug. 12, 2010]

§413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under §413.171 of this part, in the case of an ESRD facility that does not meet the performance requirements described in section 1881(h)(1)(B) of the Act for the performance year, payments otherwise made to the provider or facility section 1881(b)(14) of the Act for renal dialysis services will be reduced by up to two percent, as determined appropriate by the Secretary.

(b) Any payment reduction will apply only to the payment year involved and will not be taken into account in computing the single payment amount under this subpart for services provided in a subsequent payment year.

[76 FR 646, Jan. 5, 2011]

§413.178 [Reserved]

§413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a pediatric ESRD facility projects on the basis of prior year costs and utilization trends that it has an allowable cost per treatment higher than its prospective rate set under §413.174, and if these excess costs are attributable to one or more of the factors in §413.182, the facility may request, in accordance with paragraph (e) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with §413.176.

(d) *Payment rate exception request.* Effective October 1, 2002, CMS may approve exceptions to a pediatric ESRD facility's updated prospective payment rate, if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002. A pediatric ESRD facility may request an exception to its payment rate at any time after it is in operation for at least 12 consecutive months.

(e) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under §413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in §413.182;